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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/330,909 | 06/11/1999 | JON A. WOLFF | MIRUS.011.01 | 1001 |

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EXAMINER

WOITACH, JOSEPH T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 12/06/2001

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/330,909

Applicant(s)

WOLFF ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 12-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 12-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 14, 2001, paper number 14, has been entered.

DETAILED ACTION

This application is an original application, filed June 11, 1999, which claims benefit to provisional application 60/100,168, filed September 14, 1998.

Applicants amendment filed September 14, 2001, paper number 16 has been received and entered. The specification has been amended. Claims 7-11 have been canceled. Claims 1, 5, 6, 13, 15, 16 and 18 have been amended. Claims 21 and 22 have been added. Claims 1-6 and 12-22 are pending and currently under examination.

Response to Amendment

The declaration of Hans Herweijer filed on September 14, 2001, paper number 15, under 37 CFR 1.131 has been considered but is ineffective to overcome the Hajjar *et al.* reference. The Hajjar *et al.* reference is a 102(a) type reference, and Applicants have stated in the

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declaration that they had conceived and developed with due diligence the instantly claimed invention from the time of conception, however the declaration is signed by only one inventor, Dr. Herweijer. The execution of a 37 CFR 1.131 declaration requires the signature of each of the inventors to be effective, or an explanation of why the other inventors listed in the inventive entity are not included on the declaration.

The declaration of Hans Herweijer under 37 CFR 1.132 filed on September 14, 2001, paper number 15, is sufficient to overcome the rejection of claims 18-20 based upon lack of enablement under 35 USC 112, first paragraph. First, it is noted that claims 18-20 have been amended to encompass a process for gene expression. Upon review of the evidence presented in the declaration and the art of record, a process for delivery to in a heart muscle cell and gene expression of a protein is enabled by the guidance disclosed in the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

As note above, in view of the supplementary evidence provided in the declaration of Hans Herweijer and in view of the art of record, Applicants' arguments are found convincing for a process for gene expression. The basis of the previous rejection focused on the lack of guidance needed to overcome the art recognized unpredictability for affecting any and all gene therapy protocols. The claims have been amended to more clearly indicate the instantly claimed invention, which is a process for the delivery of polynucleotide to a heart muscle cell. The declaration provides further evidence that a transgene can be delivered and expressed by methods disclosed in the instant specification. The additional data provides evidence that the methods disclosed in the instant specification used to deliver a reporter gene construct can be extended to the delivery of other genes known and used in the art, wherein the method results in expression of protein product in a heart muscle cell.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

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Claim amendments have obviated the basis of the rejections previously set forth, therefore, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-17 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated Hajjar *et al.*

Applicants' declaration filed under 37 CFR 1.132 is not sufficient to obviate the use of the Hajjar *et al.* reference. Applicants have not provided additional arguments, therefore for the reasons of record, the rejection is maintained.

Claims 1-6 and 12-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann *et al.* (US patent # 5,922,687) and Isner *et al.* (US patent # 5,830,879)

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Applicants argue that the amendments to the claims to include the language: 'there is not more than one heart vessel occlusion site per introduction' has obviated the anticipation of both Isner *et al.* and Mann *et al.* because both teach using double balloon catheter for delivery of a nucleic acid. See Applicants amendment, bridging paragraphs on pages 5-6. Applicants arguments have been fully considered but not found persuasive.

First, it is noted that the instant disclosure contemplates the use a double balloon catheter for the deliver of a polynucleotide (for example as illustrated in figure 3). Further, the delivery of a polynucleotide by means of single balloon catheter is not even taught as a preferred embodiment, rather the support for recitation of this limitation in the claim is taken from the general description for using catheters. Finally, the limitation of 'wherein there is not more than one heart vessel occlusion site' finds only figurative support in the Example 1. In summary, in view of the general guidance given in the instant specification, a teaching wherein the use of single balloon catheter is used to deliver a polynucleotide to a heart muscle cell would anticipate claims.

As pointed out in the previous office action, Isner *et al.* teaches the delivery of a nucleic acid to the heart. Isner *et al.* deliver vectors by use of a catheter directly to a specified area and demonstrates expression of the administered gene in the heart (Isner *et al.*, Figure 12). The Isner *et al.* references provides the same level of guidance for use of catheters as the instant specification, and the examples demonstrate the delivery and expression of a nucleic acid to a heart muscle cell by means of a single balloon catheter.

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Examiner would agree that the methods taught by Mann *et al.* is an invasive means to increase the permeability of a cell, however, given the general guidance for the delivery of a polynucleotide and teachings for use of 'electroporation' and use of "'biolistic" or "gun" techniques' (specification, page 13; lines 16-20), the instantly claimed methods can reasonably be interpreted to include invasive techniques. In view of the open language of the instant method claims and the general teaching of the instant disclosure, the claimed method is not limited to any specific means of introducing a nucleic acid into a blood vessel or delivering the nucleic acid to a heart muscle cell. Further, Mann *et al.* do teach alternative means not requiring a sealed apparatus, for example the method using a catheter for delivery (Figure 4C-single balloon catheter) which is similar to that taught by Isner *et al.* Therefore, because the process disclosed by Mann *et al.* includes all the method steps recited in the claims it anticipates the claimed invention.

Claims 1-6, and 12-22 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Wolff *et al.* (US Patent 5,693,622).

Wolff *et al.* teach the delivery and expression of a polynucleotide to the cardiac muscle cell. Wolff *et al.* teach that naked polynucleotide are introduced into the cardiac tissue by myocardial injection, wherein introduction 'of the preparation into the cardiac tissue is preferably accomplished by injection from a vascular or cardiac catheter' (column 4; lines 45-51). Wolff *et al.* also provide guidance for use of liposomes to increase the uptake of a polynucleotide (column

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6; lines 18-27). Thus, Wolff *et al.* provide the necessary guidance which would anticipate the instantly claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732.

If attempts to reach the examinee by telephone are unsuccessful, the examiner's supervisor, Karen M. Hauda, can be reached on (703) 305-6608. The fax number for group 1600 is (703)308-4724.

An inquiry of a general nature or relating to the status of the application should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
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